

REMARKS

Claims 1-40 are pending in the instant application. Of these, claims 2, 5, 6, 9-13, 15, 17-20, 22-23, 25-26, 28-33, 35 and 37-40 are withdrawn from consideration pursuant to the Restriction Requirement made in the Office Action mailed 27 August 2003. In the most recent Office Action, the following rejections are repeated: claims 1, 3, 7, 8 and 16 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 6,478,804 to Vargas, et al. (hereinafter, "Vargas"); Claims 1, 21, 27 and 36 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 5,893,369 to LeMole (hereinafter, "LeMole"); Claims 1 and 14 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 5,972,024 to Northrup, III, et al. (hereinafter, "Northrup, III"). Claim 34 is newly rejected under 35 U.S.C. § 102(b) as allegedly anticipated by LeMole. Claims 4 and 24 are newly rejected under 35 U.S.C. § 103(a) as allegedly obvious over LeMole in view of U.S. Patent No. 3,123,077 to Alcamo (hereinafter, "Alcamo"). Applicant respectfully traverses all rejections, for at least the reasons set forth below.

At the outset, Applicant gratefully acknowledges the courtesy of Examiner Pantuck in granting a telephone interview with Applicant's undersigned representative, that interview held Tuesday July 20, 2004. What follows is a brief summary of that interview. In the interview, Applicant's representative highlighted certain distinguishing characteristics of claim 1 with respect to Vargas, LeMole, and Northrup, III. Also discussed was the propriety of making the most recent Office Action final, and opportunity for reconsideration. The interview was terminated at Examiner's request to review the case further, promptly after which Examiner reopened the interview to share his views. No agreement was reached.

Turning to the claims, claim 1 recites an arrangement for implementing a vascular anastomosis between a graft vessel and a target vessel comprising, *inter alia*, a wire having one end inserted into said target vessel by puncturing the wall of said vessel and exiting said vessel by puncturing the wall at a spaced location, and means for causing said wire to cut through the adjoining walls of said vessels. The Office Action avers that Vargas teaches at 110, Fig. 18, means for causing the wire to cut through adjacent walls of the vessels. However, Vargas discloses at Col. 7, lines 28-34, that 110 is a central opening in clamp 102, used to trap tissue in the clamp. Moreover, with reference to Fig. 19, an incision 118 has already been formed in the target vessel (30) when the graft vessel 32 is brought into proximity of the clamp 102. Therefore, reference numeral 110 does not anticipate the claimed structure.

Further, the Office Action avers that Vargas comprises a wire (116, Fig. 20) "inherently capable of having one end inserted into said target vessel by puncturing the wall of said vessel and exiting said vessel by puncturing the wall at a spaced location". In the first case, Vargas discloses at Figs. 20-22, that staple ends 116 of stapling device 114 are inserted through and opening formed by the incision 118, are deflected by bending features 108 of anvil arm 104, and each engages the target vessel in one and only one position. Moreover, there is no teaching or suggestion that the staple ends 116 puncture the wall of the target vessel. Therefore, the recited structure of the invention will be seen as distinguished over Vargas.

Furthermore, it has been decided by the courts that to support a *prima facie* case of anticipation by inherency, the limitation in question must "necessarily" be present in the prior art reference. *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). The examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination

that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI, 1990) (emphasis in original). In this case, there is no basis in the Office Action to conclude that the staple ends 116 necessarily puncture the target vessel in two spaced locations, particularly when the reference teaches to the contrary. “[The Office] may not... resort to speculation, unfounded assumptions, or hindsight reconstruction to support deficiencies in its factual basis.” *In re GPAC, Inc.*, 57 F.3d 1573, 35 USPQ2d 1116, 1123 (Fed. Cir. 1995).

“Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir., 1984). Therefore, because Vargas fails to teach or suggest at least the recited features discussed above, Applicant respectfully submits that claim 1 is patentably distinguished over Vargas.

Claims 3, 7, 8 and 16 each depend, either directly or indirectly, from claim 1. They are offered as patentable for at least the same reasons as independent claim 1. However, they are also separately patentable. For example, claim 3 recites the wire being longitudinally reciprocated so as to cut through the vessel walls. In contrast, there is no teaching or suggestion that the staple in Vargas is reciprocated. Rather, it is merely inserted in one direction only. Claim 9 recites the wire being manipulable to align and contact said vessels with each other. In contrast, there is no teaching or suggestion that the staples of Vargas are capable of being manipulated to align and contact the vessels with one another. Claim 16 recites the anastomosis comprising stitching sutures about the joining sides of said vessels to abut the graft vessel to the

target vessel. The Office Action offers Fig. 33 as teaching this feature. However, Fig. 33 of Vargas is a different method, and uses the sutures in place of the staples, not in addition to them.

Applicant respectfully submits that the rejection over Vargas has been obviated, and kindly requests favorable reconsideration and withdrawal.

Turning to LeMole, the Office Action avers that the reference teaches means for causing said wire to cut through the adjoining walls of said vessels within the confines of said region of contact so as to create said fluid flow passageway between said vessels, citing suture 24 of Fig. 6. Applicant respectfully disagrees. Suture 24 is placed to secure the target vases and graft vessel together to implement an anastomosis, as recited elsewhere in claim 1. Furthermore, precisely because the suture are placed to secure and seal the vessels together, there is no fluid passageway formed between the vessels by the suture 24. Any space vacated by vessel tissue when displaced by the suture is occupied by the suture itself, therefore no fluid passageway exists. With respect to claim 21, the contrast with LeMole is equally pronounced. LeMole does not teach or suggest that suture 24 cuts through the adjoining walls of the vessels to create a fluid flow passageway. To the contrary, suture 24 is provided to seal and join the vessels together, rather than to create an passageway between them. For at least these reasons, independent claims 1 and 21 will be seen as patentably distinguished over LeMole.

Claims 27, 34 and 36 each depend from independent claim 21. These claims are each separately patentable, but are offered as patentable for at least the same reasons as their underlying base claims. Therefore, Applicant respectfully submits that the rejection over LeMole has been obviated, and kindly requests favorable reconsideration and withdrawal.

With respect to Northrup, III, in contrast to claim 1, the reference teaches each suture 20 punctures a target vessel in one and only one position. Moreover, there is no teaching or suggestion of any means for causing that suture 20 to cut through the adjoining walls of the vessel to form a fluid flow passage between the vessels. Claims 14 depends from independent claim 1. Claim 14 is separately patentable, but is offered as patentable for at least the same reasons as its underlying base claims. Therefore, Applicant respectfully submits that the rejection over Northrup, III, has been obviated, and kindly requests favorable reconsideration and withdrawal.

Turning to the rejection of claims 4 and 24 as allegedly obvious over LeMole in view of Alcamo, the rejection of these claims is premised on the reading of LeMole as applied to underlying claims 1 and 21, respectively. However, Alcamo offers no teaching or suggestion to ameliorate the deficiencies of LeMole, illustrated above, with respect to these claims. It has been decided by the courts that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, Applicant respectfully submits that the rejection over LeMole and Alcamo, has been obviated, and kindly requests favorable reconsideration and withdrawal.

In the interest of brevity, Applicant has addressed only so much of the rejection(s) as is considered necessary to demonstrate the patentability of the claim(s). Applicant's failure to address any part of the rejection should not be construed as acquiescence in the propriety of such portions not addressed. Applicant maintains that the claims are patentable for reasons other than these specifically discussed, *supra*.

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In light of the foregoing, Applicant respectfully submits that all claims recite patentable subject matter, and kindly solicits an early indication of allowability. In accordance with the Restriction Requirement, Applicant kindly request rejoinder of all species claims, as generic claims 1 and 21 are shown above to be allowable. If the Examiner has any reservation in allowing the claims and believes that a telephone interview would advance prosecution, he is kindly requested to telephone the undersigned at an earliest convenience.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David J. Torrente", with a stylized flourish at the end.

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